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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,365	11/26/2001	Patrick R. Charmley	60117-99	7286

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EXAMINER	
YU, MISOOK	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 01/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/994,365	CHARMLEY ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this c mmunicati n appears n the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *13-15,17,18,20-25,28-51 and 53-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,16,19,26,27 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/1/03, 6/16/02, 2/5/02
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Exhibits A-D*.

DETAILED ACTION

Election/Restrictions

Applicant's election of group I in the reply filed on 11/05/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 13-15, 17-18, 20-25, 28-51, 53-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-57 are pending. Claims 1-12, 16, 19, 26, 27, and 52 are examined on merits.

Claim Objections

Claims 9, and 10 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 9, and 10 depend on claim 8 with the highest stringent condition, i.e., 2X SSC vs. 1X, or .2 X SSC. Some cDNA species that would hybridizes to the hybridization condition in claims 9, or 10 would not hybridizes in claim 8 condition, thus the property boundaries drawn by claim 9, and 10 are broader than the property boundary of the base claim 8.

Claim 19 is objected to because of the following informalities: Claim 19 appears to be drawn to a primer probe that hybridizes to a single stranded cDNA or its complements. However, claim 19 recites "base pairs", which means that the claimed Oligonucleotides are base paired instead of single stranded. For the purpose of this Office action, the "base pairs" in line 1 is interpreted as "bases". However, this treatment does not relieve applicant the burden of responding to this Objection. Appropriate correction is required.

Claims 19, 26, 27, and 52 are objected to because of the following informalities: The claims are still drawn to multiple inventions. Amending the claims to reflect the election would obviate this rejection. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 12, 16, 26, 27, and 52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are interpreted as drawn to genus of nucleic acid molecules with various of degrees of differences from instant SEQ ID NO:1 or nucleic acid encoding

instant SEQ ID NO:2 or 3, or vectors comprising said genus of nucleic acid molecules, host cells comprising said vector, or method of using said vector.

The applicable standard for the written description requirement can be found: MPEP 2163; University of California v. Eli Lilly, 43 USPQ2d 1398 at 1407; PTO Written Description Guidelines; Enzo Biochem Inc. v. Gen-Prove Inc., 63 USPQ2d 1609; Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111; and University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CA FC 2004).

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is partial structure in the form of percent identity or hybridization. The claims do not identify any function associated with the partial sequence. "CAN-1 polypeptide" is not an art-defined term, and the term does not appear to have any functional annotation that would be readily recognized by one skilled in the art. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the

'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of nucleic acid molecules, given that the specification has only described SEQ ID NO: 1. Therefore, only isolated nucleic acid comprising SEQ ID NO:1, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 12, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Oka et al., IDS #011 filed on 02/05/2002, Hum Mol Genet. November 1, 1999 ;8 (12):2165-70 as evidenced by NCBI accession no. AB031480 (IDS #03 filed on 02/05/2002).

Since the base claims do not have a transitional phrase in terms of the scope of not recited part of the claimed nucleic acids, the claims are broadly interpreted as drawn to an isolated nucleic acid comprising a nucleic acid encoding at least 70-90 % sequence identity to SEQ ID NO:2, or 3 polypeptide (claims 1-8, 16), or an isolated cDNA molecule encoding a CAN-1 polypeptide (claim 8) or an isolated cDNA molecule

(claims 9-10), hybridizes under the respective recited hybridization condition, or isolated cDNA molecule at least 70% identical to nucleotide #1 to 551 of SEQ ID NO:1 (claim 12),

Oka et al., (published Nov. 1, 1999; see Exhibit A, which is the publication date Hum Mol Genet containing Oka et al., cited above) teach GenBank accession no. AB031480, which is at least 99 % identical to instant SEQ ID NO:1 (see Exhibit B, sequence alignment), a nucleic acid encoding a protein, 100 % identical to the instant SEQ ID NO:2 or 3 (note Exhibits C, and D, sequence alignments). Thus, Oka et al., anticipate claims 1-10, 12, and 16.

Claims 1-3, 4-10, 12, 16, 26, and 27 are rejected under 35 U.S.C. **102(b)** as being anticipated by NCBI accession no. AC004195 (IDS #05 filed on 02/05/2002, 08-Dec-1998).

Since the base claims do not have a transitional phrase in terms of the scope of not recited part of the claimed nucleic acids, the claims are broadly interpreted as drawn to an isolated nucleic acid comprising a nucleic acid encoding at least 70-80 % sequence identity to SEQ ID NO:2, or at least 70-90 % sequence identity to SEQ ID NO:3 polypeptide (claims 1-3, 4-7, 16), or an isolated cDNA molecule encoding a CAN-1 polypeptide (claim 8) or an isolated cDNA molecule (claims 9-10), hybridizes under the respective recited hybridization condition, or isolated cDNA molecule at least 70% identical to nucleotide #1 to 551 of SEQ ID NO:1 (claim 12), vector comprising the nucleic acid of claim 1 (claim 26), or host cell comprising said vector (claim 27).

NCBI accession no. AC004195 teach a nucleic acid sequence comprising 87 % identical to instant SEQ ID NO:1 (see page 4 of Exhibit B, sequence alignment), a nucleic acid encoding a protein, 88 % identical to the instant SEQ ID NO: 2 (note Exhibits C sequence alignment), 100 % identical to instant SEQ ID NO: 3 (note Exhibit D, sequence alignment). As for claims 26, and 27 drawn to vector comprising the nucleic acid of the base claims and host cell comprising the vector, NCBI accession no. AC004195 at the heading " FEATURES source" teaches that clone that has the insert of nucleic acid deposited as NCBI accession no. AC004195 is "CGM1:A194D6", and subclone is "UWGC:y24c027", which came from clone_lib="Wash U YAC Library, and also teaches that clone is in a host cell "CGM1". The UWGC terms and definitions downloaded from url...www.genome.Washington.edu on 1/23/2005 teaches that "clones contain chosen sequencing vector and a DNA fragment which all originates from the same clone, thus the DNA that is 87 % identical to instant SEQ ID NO:1 is in a vector. Thus, NCBI accession no. AC004195., anticipate claims 1-3, 4-10, 12, 16, 26, and 27.

Claim 19 is rejected under 35 U.S.C. **102(b)** as being anticipated Bonaldo et al., (09/1996, Genome Research, vol. 6, pages 791-806).

Claim 19 is interpreted as drawn to primer of oligonucleotides between 10-100 bases that hybridize to the complement of SEQ ID NO:1.

Since instant SEQ ID NO:1 is a cDNA, which contains polyA tails at 3' end, the claimed olignonucleotides reads on the multiple oligodT primers for example, at page

801 under the heading "Construction of Directionally Cloned cDNA Libraries". Thus, Bonaldo et al., anticipates instant claim 19.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oka et al., (cited above) in view of Kuroki., (J Biol Chem. 1995 Sep 22;270(38):22428-33).

Since the specification (note claim 1) defines "CAN-1" polypeptide as a polypeptide is at least 70% identical to instant SEQ ID NO:2, the claim is interpreted as drawn to method of making instant SEQ ID NO:2 polypeptide, which is encoded by a gene located in the human chromosomal region with a susceptibility for psoriasis vulgaris.

Oka et al., teach that GenBank accession no. AB031480), a nucleic acid encoding a protein 100 % identical to the instant SEQ ID NO:2 or 3, and also discloses

that the protein is encoded by a new gene that lies in the human chromosomal region with a susceptibility for psoriasis vulgaris.

Oka et al., do not teach method of making the protein.

However, Kuroki et al., teach that once a cDNA sequence encoding a human protein is identified, making a protein from the cDNA is well known procedure, and one of ordinary skill would be motivated to make a human protein for biochemical characterization (note page 22430, left column under the heading "*Expression and Purification of ProSPA1*").

Therefore, it would have been obvious and one of ordinary skill would have been motivated to make the protein from the known cDNA sequence of Oka et al., given teaching of Oka et al., that the gene encoding the protein is located in the human chromosomal region with a susceptibility for psoriasis vulgaris. Making the protein would be accomplished with a reasonable expectation of success, given the cDNA sequence is taught by Oka et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642

MISOOK YU
PATENT EXAMINER